University Hospitals™

Fax

To Ohio Department of Health, Attn: Wanda Iacovetta
Phone
Fax 614-564-2416

From UH Cleveland Medical Center
Phone
Fax 216-201-5390

Date 4/18/18

re Plan of Correction- Follow Up
cc

Pages 14

University Hospitals Fertility Center
University Hospitals Ahuja Medical Center
Kathy Risman Pavilion
1000 Auburn Drive, Suite 310
Beachwood, OH 44122
Phone: 216-285-5028
Fax: 216-201-5390

Message

CCN: 360137

University Hospitals
Cleveland Medical Center

University Hospitals Fertility Center
Kathleen J. Sanniti
Director
1000 Auburn Drive
Kathy Risman Pavilion, Suite 310
Beachwood, OH 44122
(216) 844-1335

April 18, 2018

(Via email: ChicagoNLTCPOC@CMS.hhs.gov)
Centers for Medicare and Medicaid Services
Non-Long-Term Care Certification and Enforcement Branch
233 North Michigan Ave., Suite 600
Chicago, Illinois 60601
Attention: Pam Para, Nurse Consultant

(Via Fax: (614) 564-2416)
Ohio Department of Health
Office of Health Assurance and Licensing
Bureau of Survey and Certification
245 North High Street, 4th Floor
Columbus, Ohio 43215
Attention: Wanda Iacovetta

Re: UH Cleveland Medical Center
CCN: 360137
Survey: March 14, 2018
Plan of Correction – Follow-up

Dear Ms. Para and Ms. Iacovetta:

In response to your follow-up request regarding the Plan of Correction (POC) that was submitted to you last week, enclosed please find all of the policies referenced in the POC. You also asked for clarification as to who would be "monitoring" the plan of correction, as you indicated it was unclear as to whether it was the Lab Director or the MacDonald Quality Council. The Co-Medical Director, who is also Chair of the Department of Obstetrics & Gynecology, will be in charge of monitoring the implementation of the POC as the designee of the Laboratory Director. The Co-Medical Director will be responsible for ensuring all inservicing is completed and audits are completed in accordance with the POC. MacDonald Quality Council is the hospital's quality assurance committee. Although the Co-Medical Director will be directly responsible for monitoring the POC, the results of the monitoring will be reported to the quality assurance committee for review.

If you have any questions regarding the attached plan of correction, please contact me at (216) 844-1335 or Kathleen.Sanniti@UHhospitals.org.

Sincerely,

Kathleen J. Sanniti
Director
University Hospitals Fertility Center

Encl.
cc: James Liu, MD, Co-Medical Director
Chair, Department of Obstetrics & Gynecology

University Hospitals
Cleveland Medical Center

Policy and Procedure
Routine Maintenance and Monitoring of Cryopreservation Storage Units
Department of Reproductive Endocrinology and Infertility

1. Purpose

1.1 Embryos created through in vitro fertilization (IVF) techniques, gametes (oocytes and spermatozoa) and reproductive tissues (ovarian and testicular biopsies) from patients undergoing IVF treatment or fertility cryopreservation are stored in a biologically viable state under ultra-low temperature conditions in specialized cryopreservation storage container devices, by either immersion in liquid nitrogen (LN_2) or in the liquid nitrogen vapor phase, with temperatures ranging between -196°C to -160°C.

1.2 Routine maintenance and surveillance of the cryopreservation tanks' physical integrity and the stability of the liquid nitrogen contents of each tank are critical to assure the optimal storage environment and preservation of the gametes and reproductive tissue.

2. General

2.1 The UH Fertility Clinic has two types of cryopreservation storage container devices (cryopreservation storage tanks) in use.

2.1.1 Liquid nitrogen **"immersion"** cryopreservation tanks (also called **Liquid Nitrogen Dewars**), comprising of large metallic vacuum flasks, completely filled with LN_2 (at -196°C) in which reproductive cells or reproductive tissues are suspended in direct contact with liquid nitrogen, after being identified, labeled, and secured in metallic supports called sleeves. The temperatures of the biological materials cryopreserved in such storage units corresponds to the temperature of the surrounding liquid nitrogen (-196°C).

2.1.2 Liquid nitrogen **"vapor phase"** cryopreservation tanks, comprising of large metallic storage containers, which maintain ultra-low temperature conditions in the vapor phase of LN_2 with an automatic LN_2 filling system connected to a Liquid Nitrogen source. The reproductive cells (gametes/embryos) or tissues are stored in such tanks in open metallic racks in the vapor phase of LN_2, with temperatures ranging between -160°C to -196°C without direct contact with liquid nitrogen.

2.2 General maintenance and monitoring: **Immersion Tanks**

2.2.1 Once a week visual inspection of the tanks to rule out any physical damage to the exterior surface of the tank.

2.2.2. Daily inspection for frost or sweat present on the external tank.

2.2.2 Daily measurement of LN2 levels inside the Cryotank using a yardstick measurement device to assure a liquid nitrogen level of 14-16 inches.

2 2.2.1 Every Monday, Wednesday, and Friday liquid nitrogen is added to the tank to a level of 16 inches.

2.2.3 24 hour continuous monitoring of interior tank temperature with commercial remote alarm monitoring services (Isensix Guardian).

2.2.4 Once a month testing of the remote alarm notification system.

2.3 General maintenance and monitoring: **Vapor Phase CBS Tank**

2.3.1. Daily confirmation of vapor and signs of proper freezing.

2.3.2. Daily monitoring of the LN2 level display panel.

2.3.3. Continuous monitoring of interior tank temperature with commercial remote alarm monitoring services (Isensix Guardian).

2.3.3.1. In addition, the Andrology CBS tank temperature is monitored with commercial remote alarm monitoring service through Accsense.

2.3.4. Daily monitoring of internal tank temperature display panel.

2.3.5. Once a week visual inspection of the tank to rule out any physical damage to the exterior surface of the tank, detect any leaks at connection points of the LN2 hose lines.

2.3.6. Once a week inspection to assure electrical wires are free of damage and plugs are firmly in place.

2.3.7. Once a month testing of the remote alarm notification system (Isensix Guardian).

2.3.8. Once a month verification of the high and low level and temperature alarms.

2.3.9. Documentation of fill interval and amount of LN2 filled into vessel when the CBS vapor phase tank is in the "manual fill" mode.

2.3.10. Fluid Level and Temperature Alarm Verification

2.3.10.1. Low level alarm verification

2.3.10.2. Using the manual valve on the liquid nitrogen supply tank, turn off the liquid supply.

2.3.10.3. Create a low level alarm condition. This is done by adjusting the level set-points above the actual liquid level.

2.3.10.4. In 7-10 minutes a low alarm should occur. This will be indicated by the **LOW ALARM** text flashing and the audible alarm sounding. The remoted alarm output will activate also.

2.3.10.5. Return set points to the desired settings.

2.3.10.6. Open manual valve on supply tank to resume normal operation.

2.3.11. High Level Alarm verification

2.3.11 1. Create a high level alarm condition. This is done by adjusting the level set-points at least one inch below the actual liquid level.

2.3.11.2. In 3-5 minutes, a high alarm should occur. This will be indicated by the **HIGH ALARM** text flashing and the audible alarm sounding. The remote alarm output will activate.

2 3.11.3. Return set points to the desired settings.

2.3.11.4. Unit is now ready for normal operation.

2.3.12. Temperature Display Verification

2.3.12.1. Open storage unit lid and locate temperature sensing probes.

2.3.12.2. Carefully remove probe from protective sleeve.

2.3.12.3. Submerge the sensor probe into liquid nitrogen. The digital temperature display should read -196°Celsius (+/- 1°C).

2.3.12.4. Remove probe from liquid nitrogen and place tip of probe in an ice bath and wait 30 seconds. While the probe is submerged, the digital display should read 0° (+/- 1°C) degrees Celsius.

2.3.12.5. Check probe end for cracks or damage, return probe into its protective sleeve at the desired depth.

2.3.12.6. Close the storage unit lid and resume normal operation.

2.3.12.7. If the temperature display doesn't operate as described, there may be a problem with the probe or the probe connections. See the troubleshooting guide of the CBS

Manual (page 29) for further information if a problem is detected.

2.4. Temperature Maintenance

2.4.1. Isensix technology provides independent temperature monitoring of all IVF and Andrology tanks.

2.4.2. Accsense Remote Auto Dialer technology allows for dual temperature monitoring of the Andrology tanks.

2.4.3. The lower temperature threshold is (-) 160° Celsius.

2.4.4. Temperatures falling below the (-) 160° Celsius threshold trigger an audible alarm on the CBS vapor tank and remote alarm for both the CBS Vapor tank and Immersion tank. See Isensix Guardian for Fertility Human Tissue Monitoring policy.

2.4.5. Lab technicians document their response to the Isensix alarm system in the Isensix software.

3. Precautions

3.1. The storage tank lid remains closed except during depositing or removing a specimen and should be opened for only minimal amount of time.

3.2. Lab personnel follow the necessary safety precautions when handling liquid nitrogen. See safe handling of liquid nitrogen policy.

Owner: UH Division of REI

Date Approved: 4/7/18

Date Reviewed: 4/7/18

Approval _____, PhD, HCLD (ABB)
Clinical Lab Director

_____, MD
Medical Director

University Hospitals
Cleveland Medical Center

Policy and Procedure
Safe Handling of Liquid Nitrogen
UH Dept of Reproductive Endocrinology and Infertility

Purpose

Safety precautions are followed to avoid potential injury or damage which could result from harmful exposure to Liquid Nitrogen.

Liquid Nitrogen is extremely cold and small amounts of liquid can vaporize into large amounts of gas. Liquid Nitrogen in contact with skin or eyes may cause serious freezing (frostbite) injury. Nitrogen gas can cause suffocation without warning; as the liquid evaporates, the resulting gas tends to displace the normal air from the area. In closed areas, excessive amounts of nitrogen gas reduce the concentration of oxygen and can result in asphyxiation. Because nitrogen gas is colorless, odorless and tasteless, it cannot be detected by the human senses and will be breathed as if it were air.

1. To prevent injury by frostbite, use extreme care whenever handling liquid nitrogen.
   - 1.1 Leave no area of skin exposed.
   - 1.2 Always wear proper safety attire over clothing, a face shield, cryogenic gloves, and cryogenic apron.
   - 1.3 Use extreme care to prevent spilling and splashing liquid nitrogen during transfer.

2. To prevent the risk of asphyxiation from nitrogen vapors, store or use liquid nitrogen containers in a well-ventilated space.
   - 2.1 Oxygen sensors are in place to assure appropriate levels of Oxygen in the environment.
   - 2.2 Anyone feeling dizzy or losing consciousness should be moved immediately to a well ventilated area and an emergency response team activated.

3. In the event of a spill or splash take immediate action to prevent injury.
   - 3.1 Immediately remove any clothing or safety attire on which liquid nitrogen has spilled.
   - 3.2 Get immediate medical attention for any frostbite injuries due to liquid nitrogen.

5. Training in the safe use and handling of liquid nitrogen occurs on initial employment and then reviewed at least annually.

Owner: UH Division of REI

Date Approved: 4/7/18

Date Reviewed: 4/7/18

Approval _____, PhD, HCLD (ABB)
Clinical Lab Director

_____, MD
Medical Director

University Hospitals
Cleveland Medical Center

Policy and Procedure
Response Plan for Unresolved Alarm or Equipment Malfunction
Department of Reproductive Endocrinology and Infertility

Purpose
In the event of equipment malfunction or unresolved equipment alarms, routine measures are taken to quickly mitigate the identified problem, notify the appropriate lab leadership and assure optimal preservation of tissue.

1. In the event of an equipment alarm, routine measures are taken to resolve the alarm based on the manufacturer recommendations.
   - 1.1. Cryotank temperature alarms are to be resolved within 30 minutes.
     - 1.1.1. If alarms aren't resolved after 30 minutes, leadership is notified and steps are initiated to transfer tissue from the malfunctioning equipment to functional equipment.
   - 1.2 Incubator temperature alarms are to be resolved within 45 minutes.
     - 1.2.1. If alarms aren't resolved after 45 minutes, leadership is notified and steps are initiated to transfer tissue from the malfunctioning equipment to functional equipment.
   - 1.3. Leadership is notified immediately in the event of CBS tank liquid nitrogen level alarms and steps are initiated to transfer tissue from the malfunctioning equipment to functional equipment.
   - 1.4. Once tissue are secured, the manufacturer is notified for inspection and repair of the equipment.
   - 1.5 If repair is not possible, measures are initiated to replace the equipment as indicated.
2. In the event of equipment malfunction, routine measures are taken to notify lab leadership and initiate steps to transfer tissue from the malfunctioning equipment to functional equipment.
3. An empty Immersion tank is maintained to receive tissue that requires transfer in the event of an emergency in the embryology lab.
4. An empty vapor phase tank is maintained to receive tissue that requires transfer in the event of an emergency in the andrology lab.
5. Procedure for troubleshooting equipment failure

   5.1 Laminar Flow Hoods
   - 5.1.1. Proceed with procedure using replacement Laminar Flow Hood that is equipped with a microscope.
   - 5.1.2. Notify leadership of the equipment malfunction.
   - 5.1.3. Contact the manufacturer for equipment repair.

   5.2. Incubators
   If an incubator is giving inconsistent CO2 or temperature readings
   - 5.2.1. Remove any patient embryos or oocytes from malfunctioning incubator to a functioning incubator.
   - 5.2.2. Notify lab leadership of the equipment malfunction.
   - 5 2.3. Contact manufacturer for repair.

   5 3. Stage Warmers
   - 5.3.1. Proceed with procedure using replacement microscope with functional stage warmer.
   - 5.3.2. Transfer any embryos/oocytes to appropriate patient incubator.
   - 5.3.3. Notify lab leadership of the equipment malfunction.
   - 5.3.4. If problem persists, contact the manufacturer for equipment inspection and repair.

5.4. Refrigerator/Freezer
- 5.4.1. Remove all media/solutions from refrigerator. Place them in alternative refrigerator/freezer.
- 5.4.2. Unplug if concern for threat of electrical fire.
- 5.4.3. Contact the manufacturer or Facilities Engineering for equipment repair.

5.5. Centrifuges
- 5.5.1. In case of centrifuge failure, use the backup centrifuges.
- 5.5.2. Unplug the centrifuge if concern for threat of electrical fire.
- 5.5.3. Contact the manufacturer or Clinical Engineering for repair.

5.6. Micromanipulators/ Injectors/ Holding Injectors
- 5.6.1. Transfer any embryos / oocytes to appropriate incubator.
- 5.6.2. Replace injector with the backup.
- 5 6.3. If needle injector needs replaced, use the backup micromanipulator for the injection, using an airtight syringe for the holding pipette or Assisted Hatching mouthpiece set for manual injecting.
- 5.6.4. Notify lab leadership of alarm or equipment failure.
- 5.6.5. Contact the manufacturer for equipment repair.

5.7. Coarse/Fine Manipulators
- 5.7.1. Transfer any embryos/oocytes to appropriate incubator.
- 5.7.2. Both sets of manipulators are interchangeable for either the injector or holding side.
- 5.7.3. Use the backup manipulator setups.
- 5.7.4. When the injector manipulator malfunctions, replace it with the holding manipulator. Manually adjust the holding pipette as a stationary pipette.
- 5.7.5. If all manipulators fail, perform conventional insemination in place of ICSI.
  - 5.7.5.1. Be sure to increase the concentration of sperm accordingly.
- 5.7.6. Notify lab leadership of alarm or equipment failure.
- 5.7.7. Contact the manufacturer for equipment inspection and repair.

5.8. Cryo-storage Tanks
- 5.8.1. Troubleshoot the alarm or equipment malfunction by referencing the manufacturer's operations manual.
- 5.8.2. If unable to resolve the alarm within 30 minutes, initiate transfer of all frozen embryos, oocytes/ sperm to the backup tank.
- 5.8.3. Notify lab leadership of alarm or equipment failure.
- 5.8.4. Contact the manufacturer for equipment repair.

6. Leadership Notification Chain of Command
- 6.1 The Lab Supervisor is the first to be notified in the event of unresolved alarms or equipment malfunction.
  - 6.1.1. If the lab Supervisor is unavailable, the Lab Director is notified via phone or email.
- 6.2. The Lab Supervisor escalates unresolved concerns via the chain of command.
- 6.3. If the incident occurs after normal hours of operation, the technician on call or the staff member in nearest proximity to the IVF clinic responds to the alarm and is on site within 60 minutes of the alarm.
- 6.4. For issues involving the physical plant, notify Facilities Engineering at 593-1760 between the hours of 7a and 3:30p or 593-5777 between the hours of 3:30p and 7a.
- 6.5. For issues involving chemical safety, notify the Safety team at 593-5777.
- 6.6. For issues involving security, notify the Hospital Police Department at 593-5760.

University Hospitals
Cleveland Medical Center

Policy and Procedure
Response Plan for Unresolved Alarm or Equipment Malfunction
Department of Reproductive Endocrinology and Infertility

Owner: UH Division of REI
Date Approved: 4/17/18
Date Reviewed: 4/9/18

Approval

_____, PhD, HCLD (ABB)
Clinical Lab Director

_____, MD
Medical Director

University Hospitals
Cleveland Medical Center

UH Fertility Center

Chain of Notification for Isensix Guardian Alarm Monitoring

1.) Isensix Guardian Monitoring Devices are on:
   a.) 4 incubators in the Embryology Lab – Risman
   b.) 2 CBS vapor cryo-tanks in Embryology Lab - Risman
   c.) 5 Dewar immersion tanks in Embryology Lab - Risman
   d.) 1 CBS vapor cryo-tank in Andrology Lab – Risman
   e.) 3 Dewar immersion tanks in Andrology Lab - Risman
   f.) 1 Dewar immersion tanks in Andrology Lab - Crocker
   g.) 1 freezer in the Embryology Lab – Risman
   h.) 1 freezer in Andrology Lab – Risman
   i.) 1 freezer in Andrology lab – Crocker
   j.) 1 refrigerator in Andrology Lab - Risman
   k.) 1 refrigerator in Andrology Lab – Crocker
   l.) 1 refrigerator in Embryology Lab - Risman

2.) Isensix Guardian remote monitoring will alert by text, pager and email, on a rotating basis, the following:
   a.) Dr. James Liu, Medical Director (cell 216-407-8104; pager 30559)
   b.) Andrew Bhatnager, Lab Director (cell 239-410-3033)
   c.) Lauren Palavos, Embryologist III (cell 440-822-5907; pager 31150)
   d.) James Hamrick, Embryologist I (cell 440-991-6105; pager 31653)
   e.) Brooke Belvin, Embryologist I (cell 440-413-2663; pager 31470)
   f.) Shady Hamdallah, Embryologist I (cell 216-970-9714; pager 31344)
   g.) Kathleen Price, Andrologist I (cell 216-469-3479; pager 31907)
   h.) Rebecca Cull, Embryologist I (cell 330-998-2193; pager 31904)

3.) Staff will respond by either investigating the equipment alarm when on site and taking appropriate action or responding according to a predetermined call schedule to arrive on site. The Lab Director will be the Isensix Administrator and will be responsible for any changes in notification schedules and/or alarm parameters on the Isensix website.

   Level I – Text page sent to designated team member consisting of
   Embryologists I, II, or III
   Incubator alarm intervals are set at 15 minutes from initiation of alarm state

LN2 Cryo-tanks, refrigerators and freezers alarm intervals are set at 5 minutes from initiation of alarm state

Level II - Designated team member from Level 1 plus an additional Embryologist
Incubator alarm intervals are set at 25 minutes from initiation of alarm state
LN2 Cryo-tanks, refrigerators and freezers alarm intervals are set at 15 minutes from initiation of alarm state

Level III - Designated team from Level I & II plus Medical Director(s) and Lab Director
Incubator alarm intervals are set at 45 minutes from initiation of alarm state
LN2 Cryo-tanks, refrigerators and freezers alarm intervals are set at 30 minutes from initiation of alarm state

4.) Intervention to correct the alarm will be noted on the daily report found on the Isensix website by the staff member who addressed the issue.

5.) Any attempt to trouble shoot an unresolvable alarm must be done in consultation with the Fertility Lab Director and Medical Director.

Owner: UH Division of REI

Date Approved: March 26, 2018

Date Revised: April 7, 2018

Approval _____, MD
Medical Director

_____, PhD
Lab Director

University Hospitals
Cleveland Medical Center

Policy and Procedure
Isensix Guardian for Fertility Human Tissue Monitoring
Department of Reproductive Endocrinology and Infertility

Policy

1. Isensix is a proprietary tool assisting in monitoring and notification of staff that temperatures or other measures in a given refrigerator/freezer, cryo-tank, room, incubator or area are within or outside of its intended range or set parameters.

   1.1. Isensix is used for monitoring
      1.1.1. Room temperature and CO_2 for fertility incubators for human tissue
      1.1.2. LN2 cryo-tank temperature for fertility human tissue
      1.1.3. Refrigerators and freezers for fertility media, reagents, human tissue and previous tested blood samples

   1.2. Each piece of equipment has a wireless sensor connected to a collection point.
      1.2.1. The system monitors on a continuous basis

   1.3. Isensix equipment function verification checks are performed and documented.
      1.3.1. Yearly calibration is done by the proprietary organization, Isensix
         1.3.1.1. For areas requiring more frequent calibration per manufacturer standards or protocol, that calibration is done by Isensix.
         1.3.1.2. Documentation of calibration is maintained by Isensix online.
      1.3.2. Daily checks are done through the Isensix software on critical temperature and monitoring dependent devices as determined by the respective department. Those areas per other accreditations or standards, complete checks per that protocol.
      1.3.3. Areas with critical temperature dependent devices that are not open daily are checked by a team member when unit opens, i.e. when called in for patient service or the day the area reopens after being closed.
         1.3.3.1. Documentation is provided in the software as to alarm status during the hours/days closed.

1.4. Alarm set points are established and set in the software. Profiles and settings are dynamic and subject to change. See Attachment A
1.4.1 Alarm intervals are set by the department.
1.4.2 Alarm responders are area personnel assigned by alarm level to respond to alarms.
1.4.3 This responder list will be reviewed and updated quarterly.

1.5. Out of range temperature initiates an alarm at the collection point and notifies the assigned responders at a set interval and level.
1.5.1 Level I – Text page sent to designated team member consisting of Embryologists I, II, or III
Incubator alarm intervals are set at 15 minutes from initiation of alarm state
LN2 Cryo-tanks, refrigerators and freezers alarm intervals are set at 5 minutes from initiation of alarm state

University Hospitals
Cleveland Medical Center

Policy and Procedure
Isensix Guardian for Fertility Human Tissue Monitoring
Department of Reproductive Endocrinology and Infertility

1.5.2 Level II - Designated team member from Level 1 plus an additional Embryologist
Incubator alarm intervals are set at 25 minutes from initiation of alarm state
LN2 Cryo-tanks, refrigerators and freezers alarm intervals are set at 15 minutes from initiation of alarm state

1.5.3 Level III - Designated team from Level I & II plus Medical Director and Lab Director
Incubator alarm intervals are set at 45 minutes from initiation of alarm state
LN2 Cryo-tanks, refrigerators and freezers alarm intervals are set at 30 minutes from initiation of alarm state

1.6 Reponses to alarms that cannot be resolved:

1.6.1 Human Tissue – follows internal procedures for management of contents in room, refrigerator/freezer, incubator, or cryo-freezer when in alarm state.

1.6.2 Any attempt to trouble shoot an unresolvable alarm must be done in consultation with the Fertility Laboratory Director and Medical Director.

1.7 Follow software directions for printing temperature logs and/or actions taken.

1.7.1 All alarm notifications will be tested monthly and documented.

Owner: UH Division of REI

Date Approved: March 16, 2018

Date Revised: April 2, 2018

Approval _____, MD
Medical Director

_____, PhD
Lab Director